

K083825

510(k) SUMMARY

Expanding Orthopedics, Inc.'s EOI Spinal System

Expanding Orthopedics, Inc.  
17 West Pontotoc Avenue Suite 200  
Memphis, TN 38103

MAR 19 2009

Phone: 901-322-0332  
Facsimile: 901-322-0339

Contact Person: Raphael Meloul, COO  
Date Prepared: March 17, 2009

<b>Proprietary Name of Device and Sponsor:</b>	EOI Spinal System  Expanding Orthopedics, Inc. 17 West Pontotoc Avenue Suite 200 Memphis, TN 38103
<b>Common or Usual Name:</b>	Pedicle Screw Fixation System
<b>Classification Identification:</b>	21 CFR 888.3070
<b>Regulatory Class:</b>	Class III
<b>Device Panel</b>	Orthopedic Devices
<b>Product Code:</b>	MNI, NKB, MNH
<b>System Type:</b>	Noncervical, Pedicle System
<b>Predicate Devices</b>	CD HORIZON Spinal System from Medtronic Sofamor Danek, cleared by 510K # K063670
<b>Intended Use / Indications for Use</b>	

The EOI Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to spinal fusion of the thoracic, lumbar, and/or sacral spine.

The EOI Spinal system is limited to noncervical, pedicle use and is specifically indicated for treatment of one or more of the following acute and chronic instabilities or deformities:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
2. Spondylolisthesis;
3. Trauma (fracture or dislocation);
4. Deformities or curvatures (scoliosis, kyphosis, and/or lordosis);
5. Tumor;
6. Spinal Stenosis;
7. Pseudoarthrosis; and/or
8. Failed previous fusion.

### **Technological Characteristics**

The EOI Spinal System consists of polyaxial pedicle screws in varying diameters and lengths, Ø5.5mm straight and pre-bent rods in varying lengths, and cross connectors in adjustable widths to build a spinal construct. EOI Spinal System components are manufactured from implant grade titanium alloy [Ti-6Al-4V ELI] in accordance with ASTM F-136. Instrumentation is also available to facilitate implantation of the device components. The EOI Spinal System can be rigidly locked into a variety of configurations suitable to the patient's unique anatomy. Implant components and instrumentation are provided non-sterile and must be sterilized prior to use. As with all orthopedic implants, all implant components in this system are single-use and should never be reused.

### **Performance Data**

Mechanical Testing was conducted according to ASTM F1717 to validate the EOI Spinal System. Mechanical tests included static axial compression bending (n=6), static torsion (n=6), and dynamic axial compression bending (n=6). In all instances, the EOI Spinal System functioned as intended and performance observed was as expected. The testing demonstrated substantially equivalent mechanical properties to the previously cleared CD HORIZON Spinal System components.

### **Substantial Equivalence**

The EOI Spinal System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the EOI Spinal System and its predicate devices raise no new issues of safety or effectiveness. Thus, the EOI Spinal System is substantially equivalent to the CD HORIZON Spinal System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Expanding Orthopedics, Inc.  
% Hogan & Hartson LLP  
Ms. Janice M. Hogan  
1835 Market Street 29<sup>th</sup> Floor  
Philadelphia, Pennsylvania 19103

MAR 19 2009

Re: K083825  
Trade/Device Name: EOI Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: III  
Product Code: NKB, MNH, MNI  
Dated: December 19, 2008  
Received: December 22, 2008

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

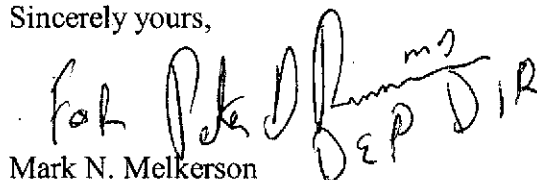
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Melkerson" with a stylized flourish at the end.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K083825

Device Name: EOI Spinal System

### Indications for Use:

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3. Trauma (fracture or dislocation);
4. Deformities or curvatures (scoliosis, kyphosis, and/or lordosis);
5. Tumor;
6. Spinal stenosis;
7. Pseudoarthrosis; and/or
8. Failed previous fusion.

Prescription Use   X  

AND/OR

Over-The-Counter Use       

(Part 21 C.F.R. 801 Subpart D)

(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Pete D. Rimmer MD  
(Division Sign-Off)

Page   1   of   1  

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number <sup>4-2</sup> K083825